Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

corporated

n and Development

20877

e: ExSept WC Skin and Wound Cleanser
: 21 CFR 880.5475
Jet Lavage
I
H
009
, 2009

Section 510(k) premarket notification of intent to market the device
ve determined the device is substantially equivalent (for the
d in the enclosure) to legally marketed predicate devices marketed in
or to May 28, 1976, the enactment date of the Medical Device
ces that have been reclassified in accordance with the provisions of
and Cosmetic Act (Act) that do not require approval of a premarket
MA). You may, therefore, market the device, subject to the general
ie Act. The general controls provisions of the Act include
registration, listing of devices, good manufacturing practice,
ns against misbranding and adulteration.

ed (see above) into either class II (Special Controls) or class III
ct to additional controls. Existing major regulations affecting your
he Code of Federal Regulations, Title 21, Parts 800 to 898. In
lish further announcements concerning your device in the Federal

DA's issuance of a substantial equivalence determination does not
le a determination that your device complies with other requirements
l statutes and regulations administered by other Federal agencies.
all the Act's requirements, including, but not limited to: registration
t 807); labeling (21 CFR Part 801); medical device reporting

vice-related adverse events) (21 CFR 803); good manufacturing
set forth in the quality systems (QS) regulation (21 CFR Part 820);
ctronic product radiation control provisions (Sections 531-542 of
050.

vice for your device on our labeling regulation (21 CFR Part 801),
r for Devices and Radiological Health's (CDRH's) Office of
5-0115. Also, please note the regulation entitled, "Misbranding by
otification" (21CFR Part 807.97). For questions regarding the
nts under the MDR regulation (21 CFR Part 803), please contact the
lance and Biometrics/Division of Postmarket Surveillance at 240-
ormation regarding the reporting of adverse events, please go to
/mdr/.

eneral information on your responsibilities under the Act from the
facturers, International and Consumer Assistance at its toll-free
or (240) 276-3150 or at its Internet address
/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

2858

and Wound Cleanser

nd Cleanser is intended for cleansing and removal of dirt, debris and
or skin abrasions, minor lacerations, minor irritations, minor cuts, and

sion of healthcare professionals, ExSept WC Skin and Wound Cleanser
chanical cleansing, debridement and removal of foreign material and
d/or dirty wounds, such as stage I-IV pressure ulcers, diabetic foot
nds, first and second degree burns, grafted and donor sites, and catheter

X AND/OR Over-The-Counter Use X
ubpart D) (21 CFR 801 Subpart C)

E BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

ence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraone for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K062656

fication

Back To Search Results

Lavage, Jet
K082858
EXSEPT WC ANTIMICROBIAL SKIN AND WOUND CLEANSER
ALCAVIS INTERNATIONAL, INC.
8322 Helgerman Court
Gaithersburg, MD 20877
Gary J Mishkin
880.5475
FQH
09/29/2008
05/27/2009
Substantially Equivalent (SE)
ttee General Hospital
General & Plastic Surgery
atus Summary Only
Summary
Traditional
No
No